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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,189	06/21/2001	Chris Somerville	056100-5022-08	7809
9629	7590	04/20/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			MC ELWAIN, ELIZABETH F	
		ART UNIT	PAPER NUMBER	
		1638		

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 26 January 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 42-46 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 42-46 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**1) Notice of References Cited (PTO-892)2) Interview Summary (PTO-1449)

## **DETAILED ACTION**

The amendment filed January 26, 2004 has been entered.

Claims 26, 27, 31 and 35-41 have been cancelled.

Claims 42-46 are newly submitted.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The statement that the claims are free of the prior art is withdrawn in view of the art rejection set forth below.

### ***Election/Restrictions***

Applicants have pointed out that the Examiner failed to respond to the traversal of the restriction requirement in the last office action. The Examiner regrets the omission and responds to the arguments with traverse below.

Applicant's election with traverse of Group IV to the extent the claims are drawn to Canola oil in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the claims "recite a specific unifying characteristic common to all of the claimed oils regardless of their source", which obviates the need for a restriction requirement and no undue burden would be required to search and examine all the claims and all inventions have the same classification. Furthermore, applicants assert that this application is a member of a family of applications that have issued as patents that were subjected to restriction requirements that divided the claims

along the lines of plant species. Finally, applicants argue that the restriction requirement will impose an undue economic hardship on the licensee.

This is not found persuasive because each oil from each plant species is distinct in chemical composition and would require a separate search, given that the claims are drawn to the oil product and the presence of hydroxy fatty acids in a seed oil is not a new characteristic that defines the claimed invention over the prior art. With regard to the other applications that have issued as patents, these applications had claims drawn to methods and to plants that comprised a novel DNA. The present claims are drawn to oil that may be extracted from plants that are transformed with a novel DNA. However, the oil itself does not comprise the same novel characteristic. The search and examination of each oil from each plant species that is claimed would require an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

### *Specification*

The objection to the disclosure is withdrawn in view of the amendment of the specification.

### *Claim Objections*

Claims 45 and 46 are objected to because of the following informalities: the claims recite non-elected plant species. Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

Claims 42-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last office action for claims 26, 27, 31 and 35-41.

Applicants' arguments filed January 26, 2004 have been fully considered but they are not persuasive.

Applicants assert that every claimed embodiment does not have to be present as an example and that the characteristics of the claimed oil are described in sufficient detail such that a person having ordinary skill in the art would recognize that Applicants were in possession of the claimed invention at the time of filing. Applicants' further state that the level of the hydroxylated fatty acids in the non-transformed plant is irrelevant that what is required is that the claimed oil have an increased level, and this can be determined by making a direct comparison of the two samples and an example of this analysis is provided in the specification. In addition, applicants argue that it is irrelevant what the level of each hydroxylated fatty acid would be in oils from other plant species, since all that is required is that the level of hydroxylated fatty acids is increased and that this determination is a simple matter and an example is provided in the specification.

Furthermore, applicants assert that other characteristics of the claimed oil may or may not have are not relevant. Applicant argues that a person skilled in the art can distinguish the claimed oil because it has an increased hydroxylated fatty acid content compared to oil obtained from seeds of the same plant species that does not have the DNA construct using the methodology set forth in the specification. Applicants also assert that the example provided of transformed *Arabidopsis* plants is accepted as a model for higher plants, including closely related species, such as *Brassica* and *Crambe*, and there is no requirement for every embodiment to be exemplified in a patent application.

The Examiner maintains that the rejection is proper for the reasons of record set forth in the last office action. The claimed oils have only been described in comparison to oil that could be isolated from the seeds of the same plant species that has not been transformed with a kappa hydroxylase gene. However, while one skilled in the art would be able to compare the seed oil of a transformed plant with the seed oil of a non-transformed plant of the same species, one skilled in the art does not have a sufficient description of the claimed oil to differentiate said oil from any other oil that is not part of such a side-by-side comparison. Applicants are claiming oil by the method by which it is made, but not by any characteristics that distinguish the claimed oil from any other oil that comprises hydroxy fatty acids.

Furthermore, one example of oil that is derived from transformed seeds of *Arabidopsis* does not define or describe oil that would be derived from any other plant species, given that each plant species differs in the particular combination and expression patterns of oil biosynthetic genes. One cannot ascertain from the chemical composition of oil from the

transformed *Arabidopsis* what the chemical composition of oil would be from any other plant species transformed with a kappa hydroxylase gene or even if any hydroxy fatty acids would be produced in other plant species. In fact, while the example of transformed *Arabidopsis* indicates that *Arabidopsis* can produce hydroxylated fatty acids, one cannot identify a specific chemical composition of oil for *Arabidopsis* transformants given that different transformants of *Arabidopsis* will have different levels of expression of the kappa hydroxylase gene, and therefore different compositions of the oil extracted from each. This is exemplified in Table 2 at page 83 of the specification, which shows the high level of variability of the hydroxy fatty acids in different *Arabidopsis* transformants. The fact that a plant has been transformed with a kappa hydroxylase gene does not provide a written description of the oil that may be extracted from the seeds of said transformed plant.

Claims 37-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for oil obtained from *Arabidopsis* that has been transformed with a nucleic acid sequence encoding a fatty acid hydroxylase, which comprises ricinoleic, lesquerolic, densipolic, and auricolic acid, does not reasonably provide enablement for oil from a plant that has been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase, including from a Canola plant, wherein said oil has a hydroxylated fatty acid content that is increased compared to the hydroxylated fatty acid content from an oil obtained from seeds of the same plant that has not been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention commensurate in scope with these claims, as stated in the last office action for claims 26, 27, 31, 35-37 and 39-41.

Applicants' arguments filed January 26, 2004 have been fully considered but they are not persuasive.

Applicants assert that they have provided an example of transforming *Arabidopsis* with a kappa hydroxylase gene to produce oil containing hydroxy fatty acids. Applicants argue that *Arabidopsis* is a model organism to study plant genetics and the oil biosynthetic genes of *Arabidopsis* are similar to those in oil producing crop plants, thus other plants transformed with the kappa hydroxylase gene will also result in the production of oil with an altered fatty acid content.

The Examiner maintains the rejection is proper for the reasons set forth in the last office action. As stated above, one example of oil that is derived from transformed seeds of *Arabidopsis* does not define or describe oil that would be derived from any other plant species, given that each plant species differs in the particular combination and expression patterns of oil biosynthetic genes and the availability of precursors for a kappa hydroxylase to act on. One cannot ascertain from the chemical composition of oil from the transformed *Arabidopsis* what the chemical composition of oil would be from any other plant species transformed with a kappa hydroxylase gene or even if any hydroxy fatty acids would be produced in other plant species. In fact, while the example of transformed *Arabidopsis* indicates that *Arabidopsis* can produce hydroxylated fatty acids, one cannot identify a specific chemical composition of oil for *Arabidopsis* transformants given that different transformants of *Arabidopsis* will have different

levels of expression of the kappa hydroxylase gene, and therefore different compositions of the oil extracted from each. The fact that one plant species has been transformed with a kappa hydroxylase gene and results in the production of hydroxy fatty acids in the seed oil does not enable the production of increased levels of hydroxy fatty acids in any or all other plant species, and it would require undue experimentation by one skilled in the art to test by trial and error the expression of a kappa hydroxylase gene in other plant species and to find which if any other plant species would be capable of producing increased levels of hydroxy fatty acids.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 42-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Badami et al (Prog. Lipid Res. 19: 119 and 132-136, 1981). Claims 45 and 46 are included in the rejection, given that the claims have not been amended to delete the non-elected plant species.

The claims are drawn to oil characterized by its hydroxy fatty acid content, which is obtained from a plant transformed with a nucleic acid coding for a kappa hydroxylase such that the hydroxy fatty acid of oil from said plant is increased relative to a non-transformed plant. The claims are product-by-process claims.

Badami et al teach seed oils from several plant families that have hydroxy fatty acids, including from the cruciferous species, *Lesquerella*, including ricinoleic, densipolic, lesquerolic, and auricolic fatty acids (see page 132).

The reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in the product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP §

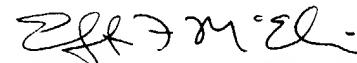
It appears that the claimed seed oil having hydroxy fatty acids is the same as, or an obvious variant of, the seed oil taught by Badami et al that contains hydroxy fatty acids, and the process of making said oil would not impart new characteristics on the oil that would differentiate it from the oil having hydroxy fatty acids that was known and taught in the prior art. Thus the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art as a whole at the time it was made, if not anticipated by Badami et al.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Elizabeth F. McElwain, Ph.D.  
Primary Examiner  
Art Unit 1638

EFM  
April 16, 2004